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Jan 3, 2002

DERWENT-ACC-NO: 2001-638851

DERWENT-WEEK: 200207

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TITLE: Diagnosing for bacterial exacerbations of chronic lung disease e.g. chronic bronchitis, comprises determining the presence or absence of, or level of elastase in sputum samples having lower respiratory tract secretions

INVENTOR: MURPHY, T F; SETHI, S

## PATENT-ASSIGNEE:

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PRIORITY-DATA: 2000US-181620P (February 10, 2000), 2001US-0780503 (February 9, 2001)

## PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
US 2002001820 A1	January 3, 2002	.	000	C12Q001/37
WO 200158338 A2	August 16, 2001	E	029	A61B000/00
AU 200151689 A	August 20, 2001		000	A61B000/00

DESIGNATED-STATES: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW

## APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
US2002001820A1	February 10, 2000	2000US-181620P	Provisional
US2002001820A1	February 9, 2001	2001US-0780503	
WO 200158338A2	February 9, 2001	2001WO-US40096	
AU 200151689A	February 9, 2001	2001AU-0051689	
AU 200151689A		WO 200158338	Based on

INT-CL (IPC): A61 B 0/00; C12 Q 1/04; C12 Q 1/37

ABSTRACTED-PUB-NO: US2002001820A

## BASIC-ABSTRACT:

NOVELTY - Diagnosing (M) bacterial exacerbations of chronic lung disease (CLD) in individuals, involves determining elastase (E) level in a sputum sample (SS) comprising lower respiratory tract secretions, and comparing it to a reference standard (RS), where an increase in (E) over RS indicates bacterial induced exacerbations of CLD.

DETAILED DESCRIPTION - Diagnosing (M) bacterial exacerbations of CLD involves:

(a) obtaining SS comprising lower respiratory tract secretions from the individual, determining the level of (E) in SS, and comparing the level of (E) in SS to RS, where an increase in the level of (E) over RS is indicative of bacterial induced exacerbations of CLD; or

(b) obtaining SS comprising lower respiratory tract secretions from the individual, and determining the presence or absence of (E) in SS by contacting the sample with an absorbent carrier coated with a chromogenic substrate for the sample, where a change in color of the absorbent carrier is indicative of bacterial induced exacerbations of CLD.

INDEPENDENT CLAIMS are also included for the following:

(1) diagnosis of *Haemophilus influenzae* induced exacerbations of CLD in an individual, which involves obtaining SS from the individual, determining the level of interleukin-8 (IL-8) in SS, and comparing the level of IL-8 in SS to a reference standard, where an increase in the IL-8 over reference standard is indicative of *H. influenzae* induced exacerbations of CLD; and

(2) diagnosis of *H. influenzae* or *Moraxella catarrhalis* induced exacerbations of CLD in an individual, which involves obtaining SS from the individual, determining the level of tumor necrosis factor- alpha (TNF- alpha ) in SS, and comparing the level of TNF- alpha in SS to a reference standard, where an increase in TNF- alpha over reference standard is indicative of *H. influenzae* or *M. catarrhalis*-induced exacerbations of CLD.

USE - The method is useful for diagnosing in an individual, exacerbations induced by bacteria, such as *H. influenzae*, *M. catarrhalis*, *Pseudomonas aeruginosa* and *Streptococcus pneumoniae*, of chronic lung disease such as chronic bronchitis (claimed), cystic fibrosis and bronchiectasis.

ADVANTAGE - The method is simple and quick, and effectively discriminates between bacterial exacerbations and non-bacterial exacerbations of chronic lung disease.  
ABSTRACTED-PUB-NO:

WO 200158338A

EQUIVALENT-ABSTRACTS:

NOVELTY - Diagnosing (M) bacterial exacerbations of chronic lung disease (CLD) in individuals, involves determining elastase (E) level in a sputum sample (SS) comprising lower respiratory tract secretions, and comparing it to a reference standard (RS), where an increase in (E) over RS indicates bacterial induced exacerbations of CLD.

DETAILED DESCRIPTION - Diagnosing (M) bacterial exacerbations of CLD involves:

(a) obtaining SS comprising lower respiratory tract secretions from the individual, determining the level of (E) in SS, and comparing the level of (E) in SS to RS, where an increase in the level of (E) over RS is indicative of bacterial induced exacerbations of CLD; or

(b) obtaining SS comprising lower respiratory tract secretions from the individual, and determining the presence or absence of (E) in SS by contacting the sample with an absorbent carrier coated with a chromogenic substrate for the sample, where a change in color of the absorbent carrier is indicative of bacterial induced exacerbations of CLD.

INDEPENDENT CLAIMS are also included for the following:

(1) diagnosis of *Haemophilus influenzae* induced exacerbations of CLD in an individual, which involves obtaining SS from the individual, determining the level of interleukin-8 (IL-8) in SS, and comparing the level of IL-8 in SS to a reference

standard, where an increase in the IL-8 over reference standard is indicative of H. influenzae induced exacerbations of CLD; and

(2) diagnosis of H. influenzae or Moraxella catarrhalis induced exacerbations of CLD in an individual, which involves obtaining SS from the individual, determining the level of tumor necrosis factor- alpha (TNF- alpha ) in SS, and comparing the level of TNF- alpha in SS to a reference standard, where an increase in TNF- alpha over reference standard is indicative of H. influenzae or M.catarrhalis-induced exacerbations of CLD.

USE - The method is useful for diagnosing in an individual, exacerbations induced by bacteria, such as H.influenzae, M.catarrhalis, Pseudomonas aeruginosa and Streptococcus pneumoniae, of chronic lung disease such as chronic bronchitis (claimed), cystic fibrosis and bronchiectasis.

ADVANTAGE - The method is simple and quick, and effectively discriminates between bacterial exacerbations and non-bacterial exacerbations of chronic lung disease.

CHOSEN-DRAWING: Dwg.0/4

TITLE-TERMS: DIAGNOSE BACTERIA CHRONIC LUNG DISEASE CHRONIC BRONCHIAL COMPRISE DETERMINE PRESENCE ABSENCE LEVEL ELASTASE SPUTUM SAMPLE LOWER RESPIRATION TRACT SECRETION

DERWENT-CLASS: B04 D16 P31

CPI-CODES: B04-B04G; B04-L05C; B11-C08; B12-K04A4; B12-K04E; D05-H04; D05-H09;

CHEMICAL-CODES:

Chemical Indexing M1 \*01\*

Fragmentation Code

F011 F012 F423 G013 G100 H2 H211 H3 H341 J0  
J014 J3 J311 J341 J373 K0 K8 K830 M210 M211  
M272 M281 M312 M314 M321 M323 M331 M332 M333 M340  
M342 M349 M381 M382 M391 M393 M423 M510 M521 M531  
M540 M781 M904 M905 N102 P831 Q233 Q505

Specfic Compounds

A5MXRK A5MXRD

Chemical Indexing M1 \*02\*

Fragmentation Code

M423 M750 M905 N102 Q233

Specfic Compounds

A0JIWK A0JIWA

Chemical Indexing M1 \*03\*

Fragmentation Code

M423 M750 M905 N102 Q233

Specfic Compounds

A00GTK A00GTA

Chemical Indexing M1 \*04\*

Fragmentation Code

M423 M750 M781 M905 N102 P831 Q233 Q505

Specfic Compounds

A09LEK A09LEA A09LED

Chemical Indexing M1 \*05\*

Fragmentation Code

M423 M750 M781 M905 N102 P831 Q233 Q505

Specfic Compounds

A06YSK A06YSA A06YSD

Chemical Indexing M6 \*06\*

Fragmentation Code

M905 P831 Q233 Q505 R515 R521 R613 R623 R627 R632  
R635 R637

SECONDARY-ACC-NO:

CPI Secondary Accession Numbers: C2001-188899

Non-CPI Secondary Accession Numbers: N2001-477560